B) Anti-HER2 specific monoclonal antibody

C) Anti-VEGF specific monoclonal antibody

D) Anti-IgE specific monoclonal antibody

E) Tumor necrosis factor immunoglobulin G1 chimera

F) Antibody-immunoadhesin chimera

(Paper 4, page 3).

In response to the requirement for restriction, Applicants elect to prosecute, without traverse, the invention of Group I, claims 1-20 and elect "A) anti-CD20 specific monoclonal antibody" as the species to be examined.

The Office has indicated that claims 1-7, 10-16, 20, 35-39 and 41-44 read on the elected embodiment and are under consideration.

Applicant has amended the specification to claim the benefit of the earlier filed provisional application filing date.

Applicant has further amended the specification to substitute page 14 as filed with replacement page 14 supplied with this response. Replacement page 14 contains the schematics of the oligosaccharide structures referred to in the text on page 14. Applicants submit that this amendment adds no new subject matter to the application as filed since the schematics merely depict oligosacchrade structures elswhere described. Further, replacement page 14 is identical to page 14 of U.S. provisional application number 60/063,871 filed October 31, 1997 to which the instant application claims benefit under 35 U.S.C. § 119.

Claim 1 has been amended to recite "containing N-linked G2 and G-2 oligosaccharide." Support for the recitation can be found at the sentence bridging pages 5 and 6 of the specification. Claim 2 has been amended to recite "wherein the N-linked G2 or G-2 oligosaccharide further comprises a bisecting N-acetylglucoseamine." Support for the recitation can be found

in the specification at, for example, page 13, lines 21-23.

INFORMATION DISCLOSURE

In accordance with Applicants duty of candor and good faith under 37 C.F.R. 1.56(a), Applicants respectfully direct the office's attention to co-pending U.S. application serial number 09/102,865 filed 23 June 1998.

1. THE REJECTION OF THE CLAIMS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

The Office has rejected claims 1-7, 10-16, 20, 35-39 and 41-44 under 35 U.S.C. § 112, second paragraph. The office contends that the claims are indefinite and ambiguous in the recitation "CH2 domain" and has recommended its replacement with "immunoglobulin CH2 domain." Applicants have amended claim 1 as suggested by the Office.

The Office further contends that the recitation "glycoprotein having at least one CH2 domain ... substantially free of the glycoprotein having at least one CH2 domain and ... its CH2 domain" is confusing. Applicants have further amended claim 1 to recite "a glycoprotein having at least one immunoglobulin CH2 domain and the composition is substantially free of the glycoprotein having an N-linked G1, G0, or G-1 oligosaccharide in the CH2 domain." Applicants submit that any ambiguity perceived by the Office has been removed by the instant amendment.

Finally, the Office contends that claims 10 and 20 contradict the compositions disclosed in pages 5 and 6 of the specification. Applicants respectfully submit that the view of the description taken by the Office fails to consider the passage at page 5, lines 25-30:

> compositions are provided comprising a glycoprotein ... wherein substantially all of the oligosaccharide is a G-2 oligosaccharide

Applicants submit that this passage provides clear, unambiguous written support for claim 10. Further, the application as a whole and in particular, the description and data accompanying Figure 4 fully support the subject matter of claim 20 as filed.

Applicants respectfully request reconsideration and withdrawal of the pending rejection in view of the amendments to the claim presented above.

2. THE REJECTION OF CLAIM 1 UNDER 35 U.S.C. § 103

The Office has rejected claims 1-7, 10-16, 20, 35-39 and 41-44 under 35 U.S.C. 103(a) as being unpatentable over Patel et al. (International Publication Number WO 97/30087) in view of Maloney et al., (1994) Blood 84:2457-2466 (hereafter, Maloney). Applicants respectfully request reconsideration.

The office contends that Patel teach a human IgG1 preparation which is substantially free of the glycoprotein containing N-linked G0, G2 and G-2 oligosaccharide domains. The Office further contends that Patel teach its use in the treatment of cancer. Patel does not disclose anti-CD 20 antibody. (Paper 4, pages 4-5). Applicants submit that Patel fails to make obvious the instantly claimed compositions, alone or in combination with Maloney. Patel fail to teach or suggest a composition comprising glycoprotein containing a G-2 oligosaccharide (claim 1 (amended), claim 10). Applicants respectfully submit that Table 1, page 20 and paragraphs 3 and 4 of page 14 referred to by the Office (Paper 4, page 4) fail to teach or make any suggestion of a G-2 oligosaccahride. Reference is made to the disclosure at pp. 43 et seq. and the description of CDC activity for G-2 glycoforms (Figure 3, for

example) of the instant application for the preparation and use of glycoprotein compositions comprising G-2 oligosaccharide. Moreover, Patel fail to teach or suggest a composition comprising an immunoglobulin CH2 domain further comprising a bisecting N-acetylglucoseamine (claim 2 (amended), claim 20). Maloney is silent on oligosaccharide structure. Therefore Patel alone or in combination with Maloney fail to teach or suggest glycoprotein compositions such as the compositions claimed. Reconsideration and withdrawal of the pending rejection of the claims on this basis is requested.

3. CONCLUSION

Applicant respectfully requests that the foregoing amendments be considered and entered in the file history of the above-identified application. It is submitted that all grounds for rejection have been removed and the claims are now in condition for allowance. It is therefore earnestly solicited that such a final favorable disposition is made. The Examiner is invited to telephone Jeffrey S. Kubinec, Esq. (Reg. No. 36,575) at (415) 225-8228 if deemed helpful to clarify and advance prosecution.

Respectfully submitted,

GENENTECH, INC.

Date: December 23, 1999 By: _____

Jeffrey S. Kubinec
Reg. No. 36,575

1 DNA Way
So. San Francisco, CA 94080-4990
Phone: (650) 225-8228
Fax: (650) 952-9881